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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/134,472    08/14/98    ROSS

D    227662XY4-S

HM22/0313

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EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

03/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/134,472

Applicant(s)

Ross et al.

Examiner

Howard Owens

Group Art Unit

1623

☒ Responsive to communication(s) filed on Feb 23, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-4, 6-11, and 23-38 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 6-11, and 23-38 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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***Response to Arguments***

The following is in response to the amendment filed 2/23/01:

An action on the merits of claims 1-4, 6-11 and 23-38 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Withdrawal of Finality**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

**35 U.S.C. 112**

**112(1),(2)**

The rejection of claims 1-11 and newly added claim 23 under 35 U.S.C. 112(1) and 112(2) has been overcome through applicant's amendment.

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5            Claims 1-4, 6-11 and 23-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,140,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to a method of effecting or treating neuronal activity in an animal with the same or analogous compounds.

10           The claims of the instant application differ only through the claim language of treating vision disorders; however, the basis of the treatment is "nerve related". As acknowledged by applicant in the interview of 11/28/00 and an amendment to overcome the 35 U.S.C. 112(1) rejection of record, the basis of the invention is treating the neurological basis or etiology of the vision disorder or memory impairment. Given  
15           that the claims of '357 are drawn to treating or effecting neuronal activity via stimulation of damaged neurons, promotion of neuronal regulation and treatment of a neurological disorder using the same compounds set forth in the instant application, one of skill in the art would certainly have a reasonable expectation of success in the use of these compounds to treat conditions which have a neurological basis as well as  
20           be provided with the motivation to use these compounds for disorders which have a neurological etiology.

             Claims 1-4, 6-11 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-23 of copending application 09/453,571. Although the conflicting claims are  
25           not identical, they are not patentably distinct from each other because they are drawn to a method of effecting or treating neuronal activity in an animal with the same or analogous N-heterocyclic compounds. The claims of the instant application differ only through the claim language of treating vision disorders; however, the basis of the treatment is "nerve related". As acknowledged by

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applicant in the interview of 11/28/00 and an amendment to overcome the 35 U.S.C. 112(1) rejection of record, the basis of the invention is treating the neurological basis or etiology of the vision disorder or memory impairment. Given that the claims of '357 are drawn to treating or effecting neuronal activity via stimulation of damaged neurons, promotion of neuronal regulation and treatment of a neurological disorder using the same compounds set forth in the instant application, one of skill in the art would certainly have a reasonable expectation of success in the use of these compounds to treat conditions which have a neurological basis as well as be provided with the motivation to use these compounds for disorders which have a neurological etiology.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**35 U.S.C. 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-11 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al., U.S. Patent No. 6,140,357.

Claims 1-4, 6-11 and 23-38 are drawn to a method of treating a nerve related vision disorder or treating memory impairment in a mammal in need thereof via administration of an N-heterocyclic ring compound containing a carbocyclic acid isostere moiety thereof attached to the 2-carbon of the N-heterocyclic ring.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Hamilton et al. teaches a method of treating or effecting neuronal activity via stimulation of damaged neurons, promotion of neuronal regulation and treatment of a neurological disorder with the analogous compounds set forth in the instant claims. Hamilton et al. teaches that these immunophilin ligands do not exert any significant immunosuppressive activity in addition to their neurotrophic activity (col. 2, line 39 - col. 18). Hamilton also teaches the use of these compounds for the treatment of memory impairment such as Alzheimer's disease (col. 2, lines 39-52 and col. 11, lines 15-17). Although Hamilton does not specifically mention vision disorders, the treatment target in Hamilton is neuronal activity and the basis of the treatment of the instant claims is neurological or "nerve related" which adequately bridges the nexus between the differences in the prior art and the invention as claimed.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the N-heterocyclic ring compound containing a carbocyclic acid to treat nerve related vision disorders or memory impairment.

A person of ordinary skill in the art would have been motivated to use the analogous compounds for the treatment of nerve related vision disorders or memory impairments given the general use of these compounds in the prior art for stimulation of damaged neurons, promotion of neuronal regulation and treatment of neurological disorders; as well as the non-immunosuppressive activity displayed by these N-heterocyclic compounds.

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Claims 1-4, 6-11 and 23-38 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/453,571 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Tuesday-Friday 9 a.m.-6:30 p.m. (EST).

- 5 If attempts to reach the examiner by telephone are unsuccessful, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

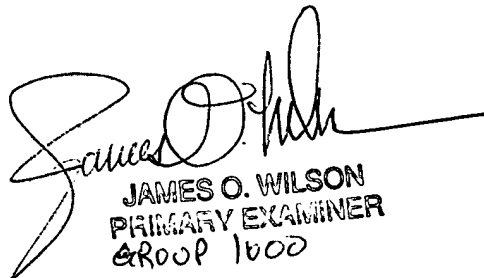
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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- 15 ***Secure and confidential access to patent application status is now available; see***  
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***Applicant(s) may pay patent maintenance fees, non-filing application fees and maintain USPTO accounts through <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm>***

  
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PRIMARY EXAMINER  
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